UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

NANCY KILMER, **Plaintiff,** **v.** **MEDTRONIC, INC.; MEDTRONIC USA, INC.; MEDTRONIC PUERTO RICO OPERATIONS, CO.; AND MEDTRONIC LOGISTICS, LLC,** **Defendants.**	**CASE NO. 1:20-cv-01277-AWI-HBK** **ORDER ON DEFENDANTS' MOTION TO DISMISS** (Doc. No. 14)

Plaintiff Nancy Kilmer has alleged that she suffered personal injuries arising from her use of a medical device that was manufactured and placed into the stream of commerce by Defendants Medtronic, Inc., Medtronic USA, Inc., Medtronic Puerto Rico Operations, Co., and Medtronic Logistics, LLC.[1] Medtronic now moves to dismiss Kilmer's claims pursuant to Federal Rule of Civil Procedure 12(b)(6). For the following reasons, the Court will grant in part and deny in part Medtronic's motion.

BACKGROUND

Kilmer filed her complaint with allegations that her Medtronic-brand SynchroMed II Programmable Implantable Infusion Pump System ("SynchroMed II Device" or "Device") caused her injuries when it twice failed to deliver prescribed medication as programmed and instead

[1] In their briefing, the parties, including Defendants (responding as one), make no distinction between the Medtronic entities. Rather, the parties treat all four named Defendants as if they are a single "Medtronic" entity. The Court will adopt that practice in this order.

delivered an opiate overdose. Doc. No. 1 ("Compl."), ¶¶ 30, 35, 39.[2] The Device is a programmable drug infusion system implanted in the body for drug delivery. Id., ¶ 11. It consists of an infusion pump connected to a thin, flexible catheter that attaches to the intrathecal space in the spinal canal. Id. In operation, an implanted Device delivers medication to the patient by way of a clinician-administered injection into the pump's reservoir fill port. Id., ¶ 12. A battery-powered machine dispenses a programmed dose of medication from the pump to the catheter (and eventually the patient's intrathecal space). Id.

Kilmer had a SynchroMed II Device implanted on April 19, 2006, to administer medication to treat lumbar disc displacement without myelopathy, post lumbar spine surgery syndrome, and chronic intractable pain. Id., ¶¶ 20–22. Her Device included a pump (Model No. 8637-20) and a catheter (Model No. 8709). Id., ¶ 22. It was initially used to administer morphine, but later used to administer hydromorphone and clonidine instead. Id., ¶ 23. On August 19, 2008, the pump in Kilmer's Device malfunctioned, causing her to suffer an onset of pain, a clammy feeling in her legs, vomiting, and withdrawal symptoms. Id., ¶ 24.

On August 8, 2012, Kilmer had her Device's pump removed and replaced with a new pump (Model No. 8637-20) that connected to her original catheter. Id., ¶ 26. The second pump was used to administer hydromorphone, clonidine, bupivacaine, and fentanyl. Id., ¶ 27. Kilmer underwent a pump refill procedure on July 22, 2014. Id., ¶ 28. Following the procedure, she was hospitalized and diagnosed with an overdose of hydromorphone after she started feeling light-headed, had a funny taste in her mouth, and became tired, dizzy, and short of breath. Id., ¶¶ 28–29. Kilmer underwent another pump refill procedure on September 7, 2018. Id., ¶ 30. After she reported feeling like there were "clouds in her head," Kilmer received an anti-overdose drug (Narcan) and was later hospitalized and diagnosed with an opiate overdose. Id., ¶¶ 30–31.

On December 20, 2018, Kilmer had her second pump removed and replaced with a new pump (Model No. 8637-20) that connected to her original catheter. Id., ¶¶ 32–33. The third pump

[2] The following factual allegations drawn from the complaint and its attached exhibits are those that are relevant for resolving Medtronic's motion. The Court construes these factual allegations as true. See Mollett v. Netflix, Inc., 795 F.3d 1062, 1065 (9th Cir. 2015).

was used to administer hydromorphone. Id., ¶ 34. Following a pump refill procedure on March 19, 2019, Kilmer reported feeling like she was "high." Id., ¶ 35. She again received Narcan and was monitored until overdose symptoms were resolved. Id. A few days later, Kilmer spoke with a Medtronic representative who informed her that Medtronic was aware of pump overdoses occurring during refill procedures but that Medtronic did not know why these overdoses were happening. Id., ¶ 36. In light of the latest malfunction, in July 2019, Kilmer had her third pump removed and replaced with a Flowonix-brand pump. Id., ¶ 38.

Kilmer filed her complaint against Medtronic on September 8, 2020. Therein, she pleads eight counts under California law: strict liability manufacturing defect (¶¶ 74–81); negligent manufacturing defect (¶¶ 82–89); strict liability failure to warn (¶¶ 90–97); negligent failure to warn (¶¶ 98–105); negligence per se (¶¶ 106–114); breach of express warranty (¶¶ 115–119); breach of implied warranty of merchantability (¶¶ 120–127); and breach of implied warranty of fitness for a particular purpose (¶¶ 128–137). Kilmer also seeks punitive damages. Id., ¶¶ 138–140. Broadly, Kilmer bases her claims on her second and third Medtronic pumps and her original catheter. Id., ¶ 39. She alleges that the pumps and catheter "failed to deliver the prescribed medication as programmed, resulting in overinfusion and causing [her] to suffer damages including pain and suffering; mental anxiety and anguish; pump removal and replacement; and medical bills in amounts to be proven at trial." Id.

Now before the Court is Medtronic's motion to dismiss. Doc. No. 14. Kilmer has filed an opposition, and Medtronic has filed a reply. Doc. Nos. 20, 25.

LEGAL STANDARD

Under Federal Rule of Civil Procedure 12(b)(6), a cause of action may be dismissed where a plaintiff fails "to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). Dismissal under Rule 12(b)(6) may be based on the lack of a cognizable legal theory or on the absence of sufficient facts alleged under a cognizable legal theory. Conservation Force v. Salazar, 646 F.3d 1240, 1242 (9th Cir. 2011); Johnson v. Riverside Healthcare Sys., LP, 534 F.3d 1116, 1121−22 (9th Cir. 2008). To survive a Rule 12(b)(6) motion for failure to allege sufficient facts, a

complaint must include a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Compliance with this rule ensures that the defendant has "fair notice of what the . . . claim is and the grounds upon which it rests." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007) (quoting Conley v. Gibson, 355 U.S. 41, 47 (1957)) (internal quotation marks omitted). Under this standard, a complaint must contain sufficient factual matter to "state a claim to relief that is plausible on its face." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (internal citations omitted). A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the alleged misconduct. Id. at 663.

In reviewing a complaint under Rule 12(b)(6), all allegations of material fact are taken as true and construed in the light most favorable to the nonmoving party. Mollett, 795 F.3d at 1065; Marceau v. Blackfeet Hous. Auth., 540 F.3d 916, 919 (9th Cir. 2008). But the Court is "not 'required to accept as true allegations that contradict exhibits attached to the Complaint or matters properly subject to judicial notice, or allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences.'" Seven Arts Filmed Entm't, Ltd. v. Content Media Corp. PLC, 733 F.3d 1251, 1254 (9th Cir. 2013) (quoted source omitted). Complaints that offer no more than "labels and conclusions" or "a formulaic recitation of the elements of a cause of action will not do." Iqbal, 556 U.S. at 678; Johnson v. Fed. Home Loan Mortg. Corp., 793 F.3d 1005, 1008 (9th Cir. 2015). Rather, "for a complaint to survive a motion to dismiss, the non-conclusory 'factual content,' and reasonable inferences from that content, must be plausibly suggestive of a claim entitling the plaintiff to relief." Moss v. U.S. Secret Serv., 572 F.3d 962, 969 (9th Cir. 2009) (quoting Iqbal, 556 U.S. at 678). If a motion to dismiss is granted, "a district court should grant leave to amend even if no request to amend the pleading was made, unless it determines that the pleading could not possibly be cured by the allegation of other facts." Henry A. v Willden, 678 F.3d 991, 1005 (9th Cir. 2012) (quoted source omitted).

REQUESTS FOR JUDICIAL NOTICE

Medtronic asks that this Court take judicial notice of various documents for purposes of

resolving its motion. Doc. No. 15. Under Federal Rule of Evidence 201, a court may take judicial of adjudicative facts if they are "not subject to reasonable dispute." Fed. R. Evid. 201(b). A fact is "not subject to reasonable dispute" if it is "generally known," or "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b)(1)–(2).

The seven documents for which Medtronic seeks judicial notice are: (1) the U.S. Food and Drug Administration ("FDA") Premarket Approval Database listing for the SynchroMed II Device, PMA No. P860004 (Doc. No. 14 at Ex. A); (2) the FDA Premarket Approval Database listing for the SynchroMed II Device, PMA No. P860004, Supplement No. S056 (Doc. No. 14 at Ex. B); (3) the FDA Premarket Approval Database listing for the SynchroMed II Device, PMA No. P860004, Supplement No. S039 (Doc. No. 14 at Ex. C); (4) an appendix comparing Kilmer's allegations regarding recalls of the SynchroMed II Device to her specific claims (Doc. No. 14 at Ex. D); (5) an appendix comparing Kilmer's allegations regarding FDA actions to her specific claims (Doc. No. 14 at Ex. E); (6) the FDA Manufacturer and User Facility Device Experience ("MAUDE") Database; and (7) a Medtronic webpage containing hyperlinks to annual neuromodulation product performance reports that were produced and published by Medtronic.

Kilmer does not object to the Court taking judicial notice of the FDA Premarket Approval Database listings. These documents, which are publicly accessible through a searchable database maintained by the FDA,[3] are matters of public record that "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Eidson v. Medtronic, Inc., 981 F. Supp. 2d 868, 878–79 (N.D. Cal. 2013). Thus, the Court will take judicial notice of Exhibits A, B, and C of Medtronic's motion.

Kilmer objects to the Court taking judicial notice of Medtronic's appendices on grounds that these are biased, self-created documents that go to the heart of the parties' disputes on

[3] The hyperlinks associated with Medtronic's first three requests are as follows:

(1) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P860004;

(2) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P860004S056; and

(3) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P860004S039.

Medtronic's motion. The Court agrees that the documents are subject to reasonable dispute and will deny Medtronic's request to take judicial notice of Exhibits D and E of its motion. See Gerritsen v. Warner Bros. Ent. Inc., 112 F. Supp. 3d 1011, 1030–31 (C.D. Cal. 2015) (declining to take notice of documents created and maintained by a party to the litigation).

Kilmer also objects to the Court taking judicial notice of the entire MAUDE Database and Medtronic's product performance reports on grounds of overbreadth, irrelevancy, and disputed factual accuracy. Medtronic responds that it only requests for the Court to take notice of the existence of these publicly accessible sources, not the truth of any matter asserted therein. The Court will deny Medtronic's request as to the performance reports on authenticity and accuracy grounds. See Gerritsen, 112 F. Supp. 3d at 1030–31. The Court will also deny Medtronic's request as to the MAUDE Database because notice of the existence of this database is not relevant to resolving this particular dispute. See Cox v. Mariposa County, 445 F. Supp. 3d 804, 808 n.2 (E.D. Cal. 2020); Bryan v. City of Carlsbad, 297 F. Supp. 3d 1107, 1115 (S.D. Cal. 2018).

DISCUSSION

Medtronic argues that all of Kilmer's claims fail as a matter of law in two separate ways. First, Medtronic contends that Kilmer's claims are expressly and impliedly preempted. Second, Medtronic contends that, even if the claims are not preempted, Kilmer's pleading is inadequate under Rule 8(a)(2). Kilmer contests each argument. Before turning to these disputes, the greater legal context in which Medtronic challenges arise must be unpacked.

A. Federal Preemption Framework

New drugs have long been subject to premarket approval under the federal Food, Drug, and Cosmetic Act ("FDCA"). Medtronic, Inc. v. Lohr, 518 U.S. 470, 475 (1996). In contrast, states were historically allowed to supervise the introduction of new medical devices. See Riegel v. Medtronic, Inc., 552 U.S. 312, 315 (2008). California was one of the states that adopted regulatory measures governing medical devices. Id. at 315–16. Things changed in 1976 when Congress "swept back some state obligations and imposed a regime of detailed federal oversight"

by enacting the Medical Device Amendments (or "MDA") to the FDCA. Id. at 316.

Of importance here, enactment of the Medical Device Amendments introduced an express preemption provision under 21 U.S.C. § 360k(a) and an implied preemption provision under 21 U.S.C. § 337(a). The express preemption provision reads in relevant part as follows:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> >
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

§ 360k(a). In Riegel, the Supreme Court articulated a two-step test for determining whether a state-law claim is expressly preempted under § 360k(a). First, the court must determine whether the FDA has established "requirements applicable to the device in question." 552 U.S. at 321–22. The FDA imposes safety and effectiveness requirements on Class III medical devices—like the SynchroMed II Device—through a rigorous evaluation known as premarket approval. Id. at 317, 322–23. "Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." Id. at 319.[4] As to the second step, if federal requirements have been established, the court must then determine whether the claim is based on state requirements regarding the "safety and effectiveness" of the device that are "different from, or in addition to," those federal requirements. Id. at 321–22. Relevant state requirements include state common-law duties. Id. at 324–25. If a state-law claim is based on different or additional state requirements, it is expressly preempted under § 360k(a). Id. at 330.

The implied preemption provision under § 337(a) states in relevant part that "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." The Supreme Court has explained that, in light of this statutory language, a state-law claim is impliedly preempted where it seeks to enforce an exclusively federal

[4] The first step is not at issue here, as the parties do not dispute that the Device is a Class III medical device that received premarket approval from the FDA. See Compl., ¶ 14.

requirement and is not grounded in traditional and independent state law. See Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 353 (2001) (contrasting impliedly preempted fraud-on-the-FDA claims with claims based on "traditional state tort law which had predated the federal enactments in questions" such as those at issue in Lohr).

Put together, the two preemption provisions leave only a "'narrow gap' through which a state-law claim must fit to escape preemption by the FDCA." Perez v. Nidek Co., 711 F.3d 1109, 1120 (9th Cir. 2013) (quoting In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig., 623 F.3d 1200, 1204 (8th Cir. 2010)). "The plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under Buckman)." Id. In other words, plaintiffs can avoid preemption if their state-law claims rest on a state-law duty that "parallels" a federal-law duty and is independent of any exclusively federal requirement. Riegel, 552 U.S. at 330; Stengel v. Medtronic Inc., 704 F.3d 1224, 1228, 1233 (9th Cir. 2013). "To properly plead parallel claims that survive preemption, a plaintiff must allege facts (1) showing an alleged violation of FDA regulations or requirements related to [the device], and (2) establishing a causal nexus between the alleged injury and the violation." Houston v. Medtronic, Inc., 957 F. Supp. 2d 1166, 1178 (C.D. Cal. 2013) (quoting Erickson v. Bos. Sci. Corp., 846 F. Supp. 2d 1085, 1092 (C.D. Cal. 2011)).

B. Kilmer's Claims

Kilmer withdraws her breach of implied warranty claims in opposition to Medtronic's motion. This leaves the other seven counts in her complaint, including the request for punitive damages.

1. Manufacturing-Defect Claims

With her first and second causes of action, Kilmer alleges that Medtronic is liable under California law for manufacturing defects in her SynchroMed II Device based on strict liability and negligence theories. Medtronic argues that Kilmer's claims are expressly and impliedly

preempted, and also fail on pleading sufficiency grounds. Kilmer disagrees on all three fronts.

California law dictates that "[a] manufacturer is strictly liable in tort when an article he places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being." Carlin v. Superior Court, 13 Cal. 4th 1104, 1110 (1996) (quoting Greenman v. Yuba Power Prods., Inc., 59 Cal. 2d 57, 62 (1963)). To plead a strict liability claim, a plaintiff must allege a defect in the manufacture of the product, causation, and injury. County of Santa Clara v. Atl. Richfield Co., 137 Cal. App. 4th 292, 318 (2006); see also In re Coordinated Latex, 99 Cal. App. 4th 594, 613 (2002) (explaining that a manufacturing-defect theory posits that a "suitable design is in place, but that the manufacturing process has in some way deviated from that design"). California law also permits recovery for manufacturing defects under general principles of negligence. Merrill v. Navegar, Inc., 26 Cal. 4th 465, 478 (2001). To plead a negligence claim, a plaintiff must allege "an additional element, namely, that the defect in the product was due to negligence of the defendant." Id. at 479 (quoted source omitted). To survive preemption on a manufacturing-defect claim, courts have required specific allegations "that the manufacturing of the device both fell short of the FDA's requirements for manufacturing and—based on the same deficiency—was defectively manufactured under California law.'" De La Paz v. Bayer Healthcare LLC, 159 F. Supp. 3d 1085, 1092 (N.D. Cal. 2016). The plaintiff cannot "incant the magic words" to avoid preemption, but must "allege facts to substantiate that [the defendant] violated a particular federal requirement applicable to the subject device." Houston, 957 F. Supp. 2d at 1178 (quoting Wolicki-Gables v. Arrow Int'l, Inc., 634 F.3d 1296, 1301 (11th Cir. 2011), and citing Simmons v. Bos. Sci. Corp., No. CV 12-7962 PA (FFMx), 2013 WL 1207421, at *4 (C.D. Cal. Mar. 25, 2013)).

For her strict liability claim, Kilmer alleges that, in manufacturing her Device, Medtronic did not comply with certain Current Good Manufacturing Practices ("CGMPs") under 21 C.F.R. Part 820. Compl., ¶ 76. She alleges that this deviation caused her Device to be deemed "adulterated" under 21 U.S.C. § 351(h), and introduced, delivered, or sold into interstate commerce as an adulterated device in violation of 21 U.S.C. § 331(a)–(c), (k). Id., ¶ 76. Based on these violations, Kilmer alleges that Medtronic also violated California Health and Safety Code

§ 111295, which makes it "unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated" (as that term is defined by California Health and Safety Code § 111260). Id., ¶ 78. In addition, Kilmer alleges that Medtronic failed to report adverse-event information to the FDA, which caused her Device to be deemed "misbranded" under 21 U.S.C. § 352(t)(2), and introduced, delivered, or sold into interstate commence as a misbranded device in violation of 21 U.S.C. § 331(a)–(c), (k). Id., ¶ 77. Kilmer alleges that, as a result of Medtronic's violations of federal and state law, her Device was not reasonably safe for its intended use and she sustained injuries and damages. Id., ¶¶ 80–81.

For her negligence claim, Kilmer alleges the same theory regarding Medtronic's adulteration and misbranding of her SynchroMed II Device in violation of federal and California law. Id., ¶¶ 84–86. She alleges that Medtronic owed her a duty under California law to use reasonable care in manufacturing her Device in compliance with federal requirements; that Medtronic was negligent in breaching that duty; and that she sustained injuries and damages as a direct and proximate result of Medtronic's negligence. Id., ¶¶ 87–89.

The Court finds that Kilmer's claims are not expressly or impliedly preempted. For both claims, Kilmer has alleged that Medtronic's failure to manufacture her Device in compliance with applicable federal requirements (and parallel state requirements) constitutes a violation of California tort law. Because the claims are not based on state requirements that are different from or in addition to the applicable federal requirements, they are not expressly preempted. See Martin v. Medtronic, Inc., No. 1:15-cv-00994-DAD-MJS, 2017 WL 825410, at *6 (E.D. Cal. Feb. 24, 2017) (holding that a similar manufacturing-defect claim based on a SynchroMed II Device escaped express preemption); Frere v. Medtronic, Inc., No. EDCV 15-02338-BRO (DTBx), 2016 WL 1533524, at *7 (C.D. Cal. Apr. 6, 2016) (same). And because the claims are based on state tort law that predates and exists independent of any exclusively federal requirement, they are not impliedly preempted. See Martin v. Medtronic, Inc., No. 1:15-cv-00994-DAD-MJS, 2017 WL 4574160, at *4 (E.D. Cal. Oct. 13, 2017) (holding that a similar manufacturing-defect claim based on a SynchroMed II Device escaped implied preemption); Frere v. Medtronic, Inc., No. CV 15-02338-BRO (DTBx), 2016 WL 9455137, at *6 (C.D. Cal. June 1, 2016) (same).

The Court also finds that Kilmer has sufficiently pleaded her manufacturing-defect causes of action. In her complaint, Kilmer alleges that, with regard to her second and third pumps, Medtronic skipped a step in the manufacturing process concerning critical internal functions related to drug reservoir levels and drug dispensing rates. Id., ¶¶ 56, 76, 84. She alleges that these functions are crucial to ensuring the correct amount of medicine is dispensed by the pump, and that as a result of this skipped step, her second and third pumps were manufactured without necessary steps designed to prevent overinfusion and to ensure accurate delivery of pain medication. Id. This, Kilmer alleges, led to her pumps miscalculating and overinfusing pain medication, which caused her injuries. Id., ¶¶ 81, 89. Kilmer supports these allegations with reference to a 2009 warning letter that the FDA issued to Medtronic following an inspection of the company's Puerto Rico manufacturing facility. Id., ¶ 52, Ex. 4. The warning letter includes the manufacturing issue that Kilmer's allegations describe as an example of Medtronic's violation of 21 C.F.R. § 820.100(a), which imposes requirements on manufacturers for establishing and maintaining procedures for implementing corrective action. Id., Ex. 4. Kilmer also supports her allegations with reference to Recall No. Z-1570-2014, which covered the kind of Medtronic pumps (Model No. 8637-20) that were used with her Device. Id., ¶ 61, Ex. 8. The recall was posted by the FDA on May 8, 2014, and terminated on September 28, 2018. Id., Ex. 8. As part of the recall process, in March 2014, Medtronic issued an urgent medical device correction letter to healthcare professionals, explaining that "Medtronic detected an upward shift in reports of occurrence of overinfusion" that "may lead to emptying of the pump prior to a planned refill and therefore may present clinically as an interruption of therapy including lack of therapeutic effect and withdrawal syndrome." Id., ¶ 61, Ex. 9. Then, in September 2016, Medtronic issued another correction letter that further explained that "[e]xamples of clinical use conditions that have been shown to increase the likelihood of overinfusion are the use of nonindicated drug formulations," among other conditions. Id., ¶ 61, Ex. 10. Kilmer alleges that she received nonindicated drug formulations and suffered two overdoses with her second pump during the time when this recall was in effect, and suffered another overdose with her third pump shortly after this recall was terminated. Id., ¶ 61.

Medtronic points out that general allegations of unspecified CGMP violations and unrelated product recalls are often found insufficient in pleading (or proving) that a federal requirement was violated. See Weber v. Allergan, Inc., 940 F.3d 1106, 1114 (9th Cir. 2019); Laux v. Mentor Worldwide, LLC, No. 2:16-cv-01026-ODW (AGR), 2017 WL 5186329, at *4 (C.D. Cal. Nov. 8, 2017). This is true, but Kilmer's complaint avoids the same fate because her claims are built on allegations of a specific CGMP violation cited by the FDA and a specific recall that addressed both the pump models that were used in her Device and the type of malfunction that she endured. When put together, Kilmer's allegations provide plausible support for the inference that Medtronic manufactured her second and third pumps in violation of federal requirements and that these manufacturing defects caused her injuries.

The Court is also not persuaded by Medtronic's argument that Kilmer's efforts to connect her specific Device to the 2009 warning letter and the 2014 recall are implausible given the temporal distance between the FDA actions and the implantation of her second and third pumps. Kilmer has alleged in sufficient detail how her Device was subject to certain manufacturing defects. Her allegations describing FDA actions that broadly addressed manufacturing issues of this kind only add support to her claims. While Kilmer will eventually have to prove that her specific Device was actually subject to particular manufacturing defects, her complaint's allegations and attached exhibits offer more than enough to survive Medtronic's dismissal motion. See Frere, 2016 WL 9455137, at *7 ("Plaintiff once again relies on various FDA warning letters, Form 483s, and recalls to support her claims. . . . Although this 'evidence' may not be conclusive at this time with respect to the actual Device implanted into Plaintiff, these documents support the inferences that Plaintiff asks this Court to make."); see also Funke v. Sorin Grp. USA, Inc., 147 F. Supp. 3d 1017, 1027 (C.D. Cal. 2015) ("[D]istrict courts 'must keep in mind that much of the product-specific information about manufacturing needed to investigate such a claim fully is kept confidential by federal law,' and that as such, 'formal discovery is necessary before a plaintiff can fairly be expected to provide a detailed statement of the specific bases for her claim.'" (quoting Bausch v. Stryker Corp., 630 F.3d 546, 558 (7th Cir. 2010))).

In sum, the Court concludes that Kilmer's manufacturing-defect claims, under both strict

liability and negligence theories, are not preempted. The Court also determines that Kilmer has plausibly stated her claims for relief. Thus, the Court will deny Medtronic's motion as to these claims.[5]

2. Failure-to-Warn Claims

With her third and fourth causes of action, Kilmer alleges that Medtronic is liable under California law for a failure to warn the FDA of adverse events based on strict liability and negligence theories. Once again, Medtronic challenges Kilmer's claims on preemption and pleading sufficiency grounds, and Kilmer opposes these efforts.

Under California law, a strict liability claim for failure to warn requires an allegation that the defendant failed to adequately warn of a known or knowable risk where that failure caused the plaintiff's injuries. Carlin, 13 Cal. 4th at 1112. California law also provides for a negligence claim where a manufacturer's failure to warn falls below the acceptable standard of care (i.e., what a reasonably prudent manufacturer would have known and warned about). Id. For both claims, a

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[5] Kilmer pleads a state-law theory of negligence per se under its own count. Compl., ¶ 113. California law does not recognize negligence per se as a separate cause of action, but rather as an evidentiary presumption that applies where (1) the defendant violated a statute, ordinance, or regulation; (2) the violation proximately caused injury; (3) the injury resulted from an occurrence that the enactment was designed to prevent; and (4) the plaintiff fits within the class of persons for whose protection the enactment was adopted. See Cal. Evid. Code § 669(a); Ramirez v. Nelson, 44 Cal. 4th 908, 917–18 (2008). If all four requirements are satisfied, the plaintiff is entitled to a presumption that the defendant failed to exercise due care; however, the plaintiff still must plead an underlying negligence claim for which the presumption is to apply. Quiroz v. Seventh Ave. Ctr., 140 Cal. App. 4th 1256, 1285–86 (2006).

Although separately pleaded, Kilmer's negligence per se theory appears to attach to her negligent manufacturing-defect claim. In line with the requirements of § 669(a), Kilmer alleges that her Device was adulterated and misbranded in violation of federal and California law, and that Medtronic's violations caused her to suffer injury. Id., ¶¶ 108–112. She also alleges that the violated provisions were designed to prevent the complained of harm and adopted for a class of persons that includes her. Id., ¶¶ 113–114.

The Court finds that Kilmer's negligence per se theory, like her negligent manufacturing-defect claim, is not preempted and sufficiently pleaded. Kilmer invokes violations of federal requirements (and parallel state requirements) for purposes of pleading a state-law theory regarding the duty to exercise reasonable care in manufacturing medical devices. See Knoppel v. St. Jude Med., Inc., No. SACV 13-383 JVS (ANx), 2013 WL 12116393, at *6 & n.10 (C.D. Cal. Sept. 24, 2013); see also Bird v. Globus Med., Inc., No. 19-cv-1024-KJM-CKD, 2020 WL 5366300, at *5 (E.D. Cal. Sept. 8, 2020); Seedman v. Cochlear Americas, No. SACV 1500366-JVS (JCGx), 2015 WL 4768239, at *11 (C.D. Cal. Aug. 10, 2015). This theory also arises from traditional state tort law, which exists independent of the FDCA. See Mize v. Mentor Worldwide LLC, 51 Cal. App. 5th 850, 865 (2020) ("Federal statutes, such as the FDCA or MDA, and federal regulations, such as those imposed by the FDA, may provide the applicable state standard of care, satisfying the first of [the § 669(a)] requirements."); Coleman v. Medtronic, Inc., 223 Cal. App. 4th 413, 433 (2014) ("California recognizes the applicability of negligence per se in a broad range of scenarios, including violation of federal law.").

manufacturer's failure to report adverse events to the FDA can form the basis of a parallel California-law claim that survives preemption. The claim escapes express preemption because device manufacturers are required to report certain adverse events to the FDA. See 21 C.F.R. §§ 803.50(a)(1), 806.10(a)(1); Stengel, 704 F.3d at 1233. The claim also escapes implied preemption because, under traditional California tort law, device manufacturers have a duty to warn of dangers. Hawkins v. Medtronic, Inc., 62 F. Supp. 3d 1144, 1165 (E.D. Cal. 2014) (citing Stengel, 704 F.3d at 1233–34 and cases applying California law). To survive a motion to dismiss, the plaintiff must allege actual instances of unreported adverse events, and factual content that supports a causal nexus between the defendant's failure to report and the injuries suffered. Hawkins v. Medtronic, Inc., No. 1:13-cv-00499-AWI-SKO, 2014 WL 346622, at *8 (E.D. Cal. Jan. 30, 2014).

For her strict liability claim, Kilmer alleges that Medtronic violated §§ 803.50(a)(1) and 806.10(a)(1) by failing to report adverse events to the FDA. Compl., ¶ 94. She alleges that had Medtronic properly reported these adverse events, she and her physicians would have learned of the risks associated with her Device and that, with this information, she would not have received a defective device or would have chosen an alternative device. Id., ¶ 96. Kilmer alleges that she sustained injuries and damages as a direct and proximate result of Medtronic's failure. Id., ¶ 97.

Kilmer's negligence theory is nearly identical to her strict liability theory. She alleges that Medtronic's violation of §§ 803.50(a)(1) and 806.10(a)(1) constituted a breach of its duty owed to her, and that this breach caused her to suffer injuries and damages. Id., ¶¶ 102–105.

The Court finds that Kilmer's failure-to-warn claims are not expressly or impliedly preempted. Like her manufacturing-defect claims, Kilmer has brought state-law claims that are predicated on alleged violations of federal requirements, not different or additional state requirements. See Martin, 2017 WL 4574160, at *5 (holding that a similar failure-to-warn claim based on a SynchroMed II Device escaped express preemption); Frere, 2016 WL 9455137, at *4–5 (same). They are also based on California tort law that predates and exists independent of the FDCA. See Martin, 2017 WL 4574160, at *5 (holding that a similar failure-to-warn claim based on a SynchroMed II Device escaped implied preemption); Frere, 2016 WL 9455137, at *6

(same).[6]

Beyond preemption, Medtronic contends that Kilmer failed to sufficiently plead both the actual adverse events that it failed to report, and how any purported failure to report caused her injury. The Court agrees that Kilmer's pleading is insufficient.

As to adverse events, Kilmer alleges that the FDA issued warning letters to Medtronic in 2007, 2009, and 2012 regarding the company's failures to report certain known adverse events, in violation of §§ 803.50(a)(1) and 806.10(a)(1). Compl., ¶¶ 51–53, 77, 94, 102. Kilmer further describes cited violations in all three letters, which are also attached to her complaint. Id., ¶¶ 51–53, Exs. 2, 4, 6. As to causation, Kilmer alleges that "[h]ad Defendants properly reported adverse events to the FDA, Plaintiff's physicians, and thus Plaintiff, would have learned of the risks associated with the SynchroMed II Device, and Plaintiff would not have received a defective device and/or would have chosen an alternative device." Id., ¶¶ 96, 104.

With these allegations (and the attached exhibits), Kilmer has both identified unreported adverse events and generally asserted that unreported adverse events caused or contributed to her injuries. Yet, her claims are still insufficiently pleaded because the required causal nexus is missing. That is, across all of her allegations, Kilmer does not clarify what specific unreported adverse event caused her to suffer her injuries. The closest she comes is with her allegations regarding the 2007 FDA warning letter, which she describes as addressing, in part, Medtronic's failure to submit timely reports to the FDA of adverse events relating to, among other things, inflammatory masses in intrathecal catheters and fractures of intrathecal catheters. Id., ¶ 77.[7] Although Kilmer generally alleges throughout her complaint that her catheter was defective and malfunctioned—see id., ¶¶ 39, 45, 55—she never specifically alleges that she suffered injuries because her catheter sustained an inflammatory mass or a facture. Telling is the contrast between Kilmer's general references to her catheter and her specific allegations regarding the particular

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[6] Medtronic cites numerous cases from other jurisdictions where failure-to-warn claims have been rejected because no state-law duty to warn exists. Yet, as Kilmer ably points out, California courts have repeatedly explained such a duty exists under California law. See Mize, 51 Cal. App. 5th at 863; Coleman, 223 Cal. App. 4th at 428–29.

[7] Kilmer's allegations regarding the 2009 and 2012 warning letters do not identify any particular adverse event that went unreported, much less an adverse event that related to her Device. See Compl., ¶¶ 51–52, 77.

manufacturing defect in her second and third pumps (as discussed above).

In her opposition brief, Kilmer supports her sufficiency argument with citation to this Court's decision in Hawkins v. Medtronic, Inc., 62 F. Supp. 3d 1144 (E.D. Cal. 2014). In Hawkins, the Court determined as sufficient a failure-to-warn pleading that relied extensively on a medical literature study that found the defendant had reported only 262 of an estimated 50,000 (at the low end) adverse events associated with the plaintiff's implanted device. Id. at 1165–67. The Court cited other decisions that had found the same study supported an inference of causation sufficient to survive a motion to dismiss. Id. at 1167 (citing Eidson v. Medtronic, Inc., 40 F. Supp. 3d 1202, 1232–34 (N.D. Cal. 2014); Houston v. Medtronic, Inc., No. 2:13-cv-01679-SVW, 2014 WL 1364455, at *7–8 (C.D. Cal. Apr. 2, 2014)). Kilmer's allegations and arguments against Medtronic's motion attempt to spell out a similar failure-to-warn theory based on repeated and prolonged underreporting of adverse events. But as things stand her efforts are not equivalent to those resting on allegations of a specific targeted study of that scale. Instead, Kilmer's complaint hews closer to the original complaint that this Court dismissed in Hawkins. There, like here, the plaintiff generally alleged that the defendants failed to report adverse events to the FDA and that these failures caused or contributed to his injuries. Hawkins, 2014 WL 346622, at *8. Also there, like here, the plaintiff did not allege any factual content that would support a causal nexus between those general allegations. Id. Without this missing link, Kilmer's complaint provides only a conclusory allegation that Medtronic's failure to report caused her injuries and her right to relief has not risen above the speculative level. Thus, the Court will dismiss Kilmer's failure-to-warn claims as not adequately pleaded. The claims will be dismissed without prejudice and Kilmer will be granted leave to amend as she still may be able to cure the pleading deficiency.

3. Breach of Express Warranty Claim

With her sixth cause of action, Kilmer alleges that Medtronic breached an express warranty related to her SynchroMed II Device. To state a claim for breach of express warranty under California law, a plaintiff must allege: (1) the exact terms of the warranty; (2) reasonable reliance thereon; and (3) a breach of warranty that proximately caused injury. Williams v. Beechnut

Nutrition Corp., 185 Cal. App. 3d 135, 142 (1986); see also Weinstat v. Dentsply Int'l, Inc., 180 Cal. App. 4th 1213, 1227 (2010) (explaining that "to prevail on a breach of express warranty claim, the plaintiff must prove (1) the seller's statements constitute an 'affirmation of fact or promise' or a 'description of the goods'; (2) the statement was 'part of the basis of the bargain'; and (3) the warranty was breached" (quoted source omitted)).

Generally, state-law claims for a breach of express warranty can survive preemption if they seek to impose liability for warranties voluntarily made outside the label and other statements that have been approved by the FDA. See Houston, 957 F. Supp. 2d at 1180–81; De La Paz v. Bayer Healthcare LLC, No. C 15–03995 WHA, 2016 WL 392972, at *10 (N.D. Cal. Feb. 2, 2016) ("The only claims for breach of the express warranty that have survived preemption are those that went 'beyond' statements approved by the FDA."). These claims escape express preemption because they do not seek to impose any requirement different from or in addition to what federal law demands. Houston, 957 F. Supp. 2d at 1180. And they escape implied preemption because such claims typically find their origin in state contract law that predates and exists independent of the FDCA. Id. at 1181.

Kilmer attaches the relevant "Limited Warranty" as an exhibit to her Complaint. Compl., ¶ 116, Ex. 13. It reads in part as follows:

> A. This Limited Warranty provides the following assurance to the patient who receives a Medtronic Neurological Implantable Pump System. The Pump System includes pumps, catheters, refill kits, and accessories, hereafter referred to as Components, unless specifically noted.
>
> (1) Should the Components fail to function within normal tolerances due to a defect in materials or workmanship within these periods:
>
> - In the case of any pump model except IsoMed, two (2) years commencing with the date of implantation;
> - In the case of the IsoMed pump, during the life of the patient into whom it is implanted;
> - In the case of the catheters and accessories, one (1) year commencing with the date of implantation;
> - In the case of the refill kits, prior to its "Use By" date.
>
> Medtronic will at its option: (a) issue a credit to the purchaser of the replacement Component equal to the Purchase Price, as defined in Subsection

> A(3), against the purchase of any same Component requested as its replacement, or (b) provide a functionally comparable replacement Component at no charge.
>
> . . . .
>
> B. To qualify for this Limited Warranty, these conditions must be met:
>
> (1) The Components must be implanted prior to their "Use By" date.
>
> (2) The Components must be used in conjunction with components compatible with the Medtronic Neurological Pump System.
>
> (3) All device registration materials must be completed and returned to Medtronic within thirty (30) days of implantation of the Components.
>
> (4) Replaced pumps must be returned to Medtronic within thirty (30) days of explantation and shall be the property of Medtronic. The catheter, refill kits, or accessory, or portion thereof, must be returned to Medtronic within thirty (30) days after discovery of the defect and shall be the property of Medtronic, and if not explanted, the serial number or lot number must be provided to Medtronic instead.
>
> (5) The use of medication with the Components must be used in accordance with the labeling and instructions for use provided with the Components.

Id., Ex. 13.

Kilmer alleges that she received this warranty along with her Device and relied on it when deciding to have her Device implanted. Id., ¶ 117. She alleges that Medtronic breached the warranty when Medtronic did not refund or replace at no charge the third pump, which failed because of manufacturing defects less than two years after it was implanted. Id., ¶ 118. She also alleges that she met the qualifying conditions set forth in Section B of the warranty. Id.

The parties debate whether the warranty was amongst the labeling or statements related to the Device that have been approved by the FDA. Kilmer emphasizes that she has not made an allegation suggesting this to be so. Cf. Martin, 2017 WL 825410, at *8 (concluding a warranty claim was expressly preempted where the complaint described warranties made "by way of written literature, including but not limited to product labeling, patient package inserts, articles in medical journals, advertising and/or other documents and/or promotional materials"). In its reply brief, Medtronic cites a pair of FDA guidance documents that generally address medical device labeling and premarket approval applications, and suggests that judicial notice can be taken of these materials. But even if such notice is taken, Medtronic's argument is not helped because

these documents say nothing particular to the SynchroMed II Device and its labeling and FDA approval. Nor for that matter has Medtronic directed the Court to anything in the complaint or its attached exhibits or other judicially noticed documents that supports its contentions that the warranty on which Kilmer bases her claim was approved by the FDA. Cf. De La Paz, 159 F. Supp. 3d at 1098 (using judicially noticed documents to determine that purported warranties were statements that had been approved or required by the FDA). Without more, the Court will reject Medtronic's conclusory assertion that Kilmer's claim is expressly preempted.[8]

The Court also rejects Medtronic's argument that Kilmer's pleading is insufficient. Medtronic focuses on Kilmer's allegations that her Device was used to administer a "non-indicated medication," and argues that these statements indicate that she failed to meet one of the qualifying conditions of the warranty. Medtronic separately contends that Kilmer has not sufficiently pleaded her compliance with the other four qualifying conditions. Although Kilmer has alleged that her Device was used to administer nonindicated medication—see Compl., ¶ 61—Medtronic has not shown here that this allegation alone definitively establishes that she did not use her Device "in accordance with the labeling and instructions for use," as the warranty requires. This may prove true in the course of further proceedings. At this stage, however, the Court takes as true Kilmer's uncontroverted allegation that she satisfied all of the qualifying conditions and finds that she has sufficiently stated her claim.

4. Punitive Damages Request

Kilmer seeks punitive damages on allegations that Medtronic knew or should have known that her SynchroMed II Device was defective and presented her with an unreasonable risk of harm. Compl., ¶ 139. California law allows for punitive damages to be recovered for products-liability claims where a defendant engaged in oppression, fraud, or malice. See Cal. Civ. Code § 3294(a); Boeken v. Philip Morris, Inc., 127 Cal. App. 4th 1640, 1690 (2005); Grimshaw v. Ford Motor Co.,

[8] Although Medtronic focuses its substantive implied-preemption argument exclusively on Kilmer's other claims, it also broadly states in its motion that all of Kilmer's claims are impliedly preempted. In so far as Medtronic's argument is read at its broadest, the Court finds that Kilmer's claim is not impliedly preempted because it arises from traditional state law that exists independent of the FDCA. Houston, 957 F. Supp. 2d at 1180.

119 Cal. App. 3d 757, 809–10 (Ct. App. 1981). Under federal pleading standards, "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally" so long as a plausible claim for relief is still articulated. Coppola v. Smith, 982 F. Supp. 2d 1133, 1144 (E.D. Cal. 2013) (quoting Fed. R. Civ. P. 9(b)). Kilmer alleges that Medtronic's conduct (as described throughout the complaint) demonstrates "a malicious, despicable, willful, and conscious disregard of the safety of those persons who might foreseeably have been harmed by the SynchroMed II Device." Compl., ¶ 140. The Court finds the derivative pleading sufficient and will deny Medtronic's motion on this count.

ORDER

Accordingly, IT IS HEREBY ORDERED that:

1. Medtronic's motion to dismiss (Doc. No. 14) is GRANTED in part and DENIED in part.
2. Kilmer's causes of action for strict liability failure to warn (Count III) and negligent failure to warn (Count IV) are DISMISSED without prejudice.
3. Kilmer's causes of action for breach of the implied warranty of merchantability (Count VII) and breach of the implied warranty of fitness for a particular purpose (Count VIII) are WITHDRAWN.
4. Kilmer is GRANTED leave to file an amended complaint. If Kilmer elects to file an amended complaint, she must do so within thirty days of service of this order.

IT IS SO ORDERED.

Dated: April 13, 2021

SENIOR DISTRICT JUDGE